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Sanitary/Phytosanitary/Food Safety

Revision of Specification and Standards for Food Additives

2005

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Report Highlights:

Japan invited foreign embassies to comment on revision of the specification and standards for food additives. The deadline for submitting these comments is December 22, 2005. This proposal will be open for comments again when it is submitted to the WTO.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Tokyo [JA1]
[JA]

On December 8, 2005, the Ministry of Health, Labor, and Welfare (MHLW) invited foreign Embassies in Tokyo to comment on revision of specification and standards for food additives. Details on this proposed action given by MHLW are shown below. Foreign governments have until December 22, 2005 to comment.

All interested parties are encouraged to send their comments, well before the deadline, for consideration to USDA's Foreign Agricultural Service. The office responsible for the comments is:

Food Safety and Technical Services
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USDA Foreign Agricultural Service
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1. Introduction

Since 1960 when the first edition of the Japanese official compilation was prepared, the compilation has been updated regularly. The last edition, which was the seventh edition, was published in 1999. This newly proposed revision will be carried out to contain specifications and standards that have been newly established or modified since then.

2. Purpose

The official compilation of food additives will be revised to:

A. Develop compositional specifications for non-synthetic food additives by establishing specifications for 61 existing food additives and one ordinary food used as food additive and containing the established standards in the official compilation. In the Food Sanitation Law, "existing food additives" means natural additives that have been manufactured, distributed, and used before the 1995 amendment of the Food Sanitation Law. "Ordinary foods used as food additives" means substances that are generally consumed as food but also used as a food additive.

B. Contain compositional specifications for food additives which have been designated by the Minister of Health, Labour and Welfare after the publication of the seventh edition and use standards revised for food additives which have already been designated.

C. Reflect advances in science and technology and new knowledge in the existing general testing methods, standards, and specifications for food additives, and make them more appropriate in light of the global level of science.

D. Introduce infrared spectrophotometry in identification tests wherever possible, to improve test accuracy.

E. Review the existing standards and specifications based on standards established by the international evaluating organization (Joint FAO/WHO Expert Committee on Food Additives) for the purpose of international harmonization.

F. Modify the ways chemical names and structural formulas are described and the wording to improve convenience of the official compilation.

3. Outline of the revision

A. Compositional specifications for 63 substances (61 additives) and 1 ordinary food used as food additive will be newly established and listed.

i. Substance name

See the next page of this document.

ii. Definition

The descriptions of sources and producing methods have been according to the List of Existing Food Additives and the detailed list of existing food additives, which appear in Attachment 1 to Director-General Notice No. 56, "Food Additive Labeling under the Food Sanitation Law" (Department of Food Safety, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, May 23, 1997).

Nomenclatures have been added.

iii. Identification tests

The chemical characteristics of individual substances and the quality commercial products have been considered.

iv. Purity tests

Specifications have been established for categories including heavy metals, lead, arsenic, and microorganism, in light of the quality of commercial products.

B. The standards and specifications for 20 food additives, which have been designated after the publication of the seventh edition, will be contained. The use standards that have were revised after the latest publication will be contained.

C. General testing methods applied commonly to the substances and testing method applied to individual substances in the monographs will be revised to improve the operability and accuracy.

D. Infrared spectrophotometry will be newly introduced in the identification tests of 36 substances. Reference spectra which appear in the seventh edition will be reviewed, and the eighth edition will contain 56 spectra in total.

E. Harmful reagents will be replaced with less harmful ones in order to improve the safety of examinations. Some tests for taste, which inflict unnecessary burden on examiners, will be abolished.

F. Compositional specifications, especially purity tests, will be revised in order to harmonize Japanese standards with international standards, and to reflect market distribution conditions.

G. Nomenclatures will be added, in order to clarify definitions of source plants and microorganisms.

H. The IUPAC (International Union of Pure and Applied Chemistry) nomenclature system will be introduced for substance names. For some reagents, Japan Industrial Standard Numbers will be added and the wording and description of structural formulas will be standardized, in order to improve convenience.

List of 61 Existing food additives (63 substances) and 1 ordinary food used as food additive

1. Red Cabbage Color (food ingredient)¹

2. N-Acetylglucosamine

3. 5'-Adenylic Acid
4. L-Arabinose
5. Inositol (Myo-Inositol)
6. Acid Clay
7. Curdlan
8. Licorice Extract
9. Gardenia Blue
10. Gardenia Red
11. Gardenia Yellow
12. α -Glucosyltransferase Treated Stevia
13. Enzymatically Modified Isoquercitrin
14. Enzymatically Modified Hesperidin
15. Enzymatically Decomposed Lecithin
16. Yeast Cell Wall
17. Bone Charcoal
18. Psyllium Seed Gum
19. Activated Acid Clay
20. Cyanocobalamin
21. Cyclodextrin [α -Cyclodextrin, γ -Cyclodextrin]
22. 5'-Cytidylic Acid
23. Calcinated Calcium [Calcinated Shell Calcium, Calcinated Eggshell Calcium]
24. Milt Protein
25. Stevia Extract
26. Spirulina Color
27. Crude Magnesium Chloride
28. Taurine (Extract)
29. Tamarind Seed Gum
30. Tara Gum
31. Thujaplicin (Extract)
32. Dextran
33. Tocotrienol
34. d- γ -Tocopherol
35. d-d-Tocopherol
36. Tomato Color
37. Bacillus Natto Gum
38. Naringin
39. Paraffin Wax
40. Microfibrillated Cellulose
41. Fukuronori Extarct
42. Pullulan
43. Bataine
44. Haematococcus Algae Color
45. Heme Iron
46. Bentonite
47. e-Polylysine
48. Microcrystalline Wax
49. Macrophomopsis Gum
50. Purple Sweet Potato Color
51. Purple Corn Color
52. Menaquinone
53. Chinese Bayberry Extract
54. Yucca Foam Extract
55. Rakanka Extract
56. Lac Color

57. Lanolin
58. Rhamsan Gum (Rhamsan Polysaccharides)
59. Lysozyme
60. D-Ribose
61. Enzymatically Decomposed Rutin
62. Enju Extract

¹: Ordinary food used as food additive

The revisions of general tests and specifications for individual food additives are outlined in Tables 1-3.

Table1

General Test s

Test methods	Outline of revision
1. Sulfite Determination	
2. Ion Chromatography	Minor changes in wording.
3. Liquid Chromatography	Minor changes in wording.
4. Chloride Limit Test	
5. Flame Coloration Test	
6. Ash and Acid-Insoluble Ash Limit Test	Minor changes in wording.
7. Gas Chromatography	Minor changes in Wording. The scope of specified apparatus is expanded. The standard addition method is added to Assay.
8. Calcium Salt Determination	
9. Loss on Dry	Minor changes in wording.
10. Spectrophotometry	The name of test is changed from Spectrophotometry to Ultraviolet-visible Spectrophotometry, and this test is placed just after Turbidity. Minor changes in wording.
11. Congealing Point	Minor changes in wording.
12. Loss on Ignition	Minor changes in wording.
13. Residue on Ignition	Minor changes in wording.
14. Refractive Index	Minor changes in wording.
15. Atomic Absorption Spectrophotometry	Minor changes in wording.
16. Flavoring Substances Tests	The scope of specified detectors is expanded. Minor changes in wording.
17. Color Value Test	
18. Heavy Metals Limit Test	
19. Water Determination (Karl Fisher Method)	Minor changes in wording.
20. Infrared Spectrophotometry	The procedure is modified. The description of measuring methods is made more detailed.
21. Turbidity Test	The specifications for reference solutions are modified. (Reference solutions that are used to determine whether the sample solution is "clear" or "almost clear.")
22. Coloring Matter Tests	Minor changes in wording.
23. Coloring Matter Aluminum Lake Tests	Minor changes in wording.
24. Nitrogen Determination	Minor changes in wording.
25. Qualitative Tests	

26. Iron Limit Test	
27. Lead Limit Test (Atomic Absorption Spectrophotometry)	Minor changes in wording.
28. Viscosity	
29. Thin-Layer Chromatography	The scope of specified thin-layer plates is expanded.
30. Quantitative Test for Generated Gas	
31. pH Determination	
32. Specific Gravity	Minor changes in wording.
33. Microbial Limit Tests	Media for xerophilous fungi are added. The Serial Dilution Method is modified. The table of most probable number (MPN) is modified. The scope of specified strains for tests is expanded. The coliform test is slightly modified. Other wording is changed.
34. Optical Specific Rotation	
35. Arsenic Limit Test	
36. Boiling Point and Amount of Distillate	The test name is changed to Boiling Point and Distillation Range Test. Minor changes in wording.
37. Methoxyl Determination	The Japanese test name is changed (English name not changed).
38. Melting Point	
39. Inductively Coupled Plasma Atomic Emission Spectrometry	Minor changes in wording.
40. Fats and Related Substances Tests	An iodine value test is added. Minor changes in wording.
41. Sulfate Limit Test	
42. Readily Carbonizable Substances Test	
43. Paper Chromatography	

Each number preceding the individual testing methods is the reference number used in the Japanese version. These methods are described in alphabetical order in the English version.

Table2

Outline of the Revision of Monographs

Substance name	Category	Outline of revision	Reason of revision
Sodium Chloride	Assay	The blank test abolished.	The conduct of the blank test is impossible since the color does not disappear.
Aspartame	Identification IR Spectrophotometry ¹	Comparison to reference spectrum → Identification by wavenumbers (Paste Method)	Improvement of the accuracy of identification. Spectrum varies depending on crystal form.
	Identification	Test (2), ninhydrin method added.	This test is necessary to ensure the identification of Aspartame.
Ethyl Acetoacetate	Identification (1), (2)	Qualitative reaction → Comparison to IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Acetophenone	Identification (IR Spectrophotometry)	Identification by wavenumbers → Comparison to IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
α-Amylcinnamaldehyde	Identification (1), (2)	Qualitative reaction → Comparison to IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
DL-Alanine	Identification (1), (2)	Qualitative reaction → Comparison to IR reference spectrum (KBr Method ²)	Improvement of the accuracy of identification.
	Purity (4) Heavy metals	Method 4 → Method 1	An easier method introduced. Harmonization with the method for L-Alanine.
Gum Arabic	Definition	Source plant names (Acacia senegal and seyal) added.	There are two sources: senegal and seyal.
	Identification	Test (3), rotatory power determination added.	Distinction between senegal and seyal.
	Purity (4) Heavy metals	Abolished.	Harmonization with JECFA ³ standards.
	Purity (5) Lead	Limit is changed. (Not more than 10 µg/g → Not more than 2.0 µg/g)	Harmonization with JECFA standards.
Propylene Glycol Alginate	Purity (1) Esterification value	Not less than 75.0% → Not less than 40.0%	Harmonization with FCC ⁴ methods.
Isoeugenol	Identification (IR Spectrophotometry)	Identification by wavenumbers → Comparison to IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
γ-Undecalactone	Identification	Qualitative reaction → IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.

Ethylvanillin	Identification (IR Spectrophotometry)	Identification by IR reference spectrum (KBr Method → Paste Method)	Improvement of the accuracy of identification.
Potassium Chlorite	Purity (2) Bromide	Solvent replaced by less harmful one.	Elimination of harmful reagents.
Eugenol	Identification (IR Spectrophotometry)	Identification by wavenumbers → Use of IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Ornithine	Identification (1), (2)	Qualitative reaction → Comparison to IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Ethyl Octanoate	Identification (1), (2)	Current reaction → Comparison to IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Processed Eucheuma Algae	Definition	Source plant name added.	Addition of scientific name.
	Identification (2)	Test method modified.	A white precipitation is not produced.
	Purity (1) Viscosity	Heating process before sampling eliminated. Sampling of the amount equivalent to the dry weight.	Viscosity falls during drying.
	Purity (2) Calcium	Purified water → Water	Conformity of wording.
	Purity (3) Sodium	Purified water → Water	Conformity of wording.
	Purity (5) Acid-insoluble matter	Distilled water → Water	Conformity of wording.
	Purity (7) Lead	Limit changed. (Not more than 10 µg/g → Not more than 5.0 µg/g)	Harmonization with JECFA standards.
Gum Ghatti	Purity (Residual solvent: 2-Propanol and methanol)	Specification newly set. (Not more than 0.10% in total)	Harmonization with JECFA standards.
	Identification (2)	Test method modified.	A white precipitation is not produced.
	Purity (7) 4-methylimidazole	TLC ⁵ → GC ⁶	Elimination of harmful reagents.
	Purity (7) 4-methylimidazole	TLC → GC	Elimination of harmful reagents.
	Purity (7) 4-methylimidazole	TLC → GC	Elimination of harmful reagents.
	Identification (2)	Test method modified.	It is often difficult to determine whether it is swollen.
	Calcium Carboxymethylcellulose	Qualitative reaction → Comparison to IR reference spectrum (KBr Method after drying)	Improvement of the accuracy of identification.
Sodium Carboxymethylcellulose	Identification (2)	Test method modified.	Sample preparation is inadequate.
	Purity (4) Heavy metals	Specification abolished.	Harmonization with JECFA standards.
	Purity (Lead)	Specification newly set. (Not more than 2.0 µg/g)	Harmonization with FCC methods.
	Identification (1)	Qualitative reaction → IR reference spectrum (KBr Method after dried)	Improvement of the accuracy of identification.
	Purity (4) Heavy metals	Specification abolished.	Harmonization with FCC methods.
β-Carotene	Identification (2)	Solvent replaced by less harmful one.	Elimination of harmful reagents.
	Purity (2) Clarity of solution	Solvent replaced by less harmful one.	Elimination of harmful reagents.
	Purity (5) Absorbance ratio	Solvent replaced by less harmful one.	Elimination of harmful reagents.
	Assay	Solvent replaced by less harmful one.	Elimination of harmful reagents.
	Identification (1)	Reagents replaced by less harmful another ones.	Elimination of harmful reagents.
Carob Bean Gum	Description	Color range expanded to white.	Color may change depending of particle size and the degree of refinement.
	Identification (2)	Solution heated and cooled in Identification (1) is used as the test solution.	Prompt and absolute formation of gel.
	Purity (2) Starch	Sample weighing procedure modified.	It is not necessary to weigh the sample accurately.
	Purity (4) Heavy metals	Specification abolished.	Harmonization with JECFA standards.
	Purity (5) Lead	Limit is revised. (Not more than 10.0 µg/g → Not more than 2.0 µg/g)	Harmonization with JECFA standards.
	Purity (Residual solvent: 2-Propanol)	Specification added. (Not more than 1.0%)	Harmonization with JECFA standards.
	Identification (1), (2)	Qualitative reaction → IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Isoamyl Formate	Identification (1), (2)	Qualitative reaction → IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
	Definition	Scientific name added.	Scientific name added.
	Description	Color range expanded to white.	Color may change depending of particle size and the degree of refinement.
	Purity (2) Pyruvic acid	Specification abolished.	Specification for pyruvic acid is not fit to identify Xanthan Gum.
	Purity (3) Heavy metals	Specification abolished.	Harmonization with JECFA standards.
	Purity (4) Lead	Limit is revised. (Not more than 5.0 µg/g → Not more than 2.0 µg/g)	Harmonization with JECFA standards.
	Purity (Residual solvent: 2-Propanol)	Specification newly set. (Not more than 0.05%)	Harmonization with JECFA standards.
Xylitol	Identification (3) (IR Spectrophotometry)	Sample dried before test.	Improvement of the accuracy of identification.

Gum Gum	Definition	Scientific name added.	学名追加
	Description	Color range expanded to white. Description of odor modified.	Color may change depending of particle size and the degree of refinement. Conformity of the specification to the odor of commercial products.
	Identification (2)	Solution heated and cooled in Identification (1) is used as the test solution.	Prompt and absolute formation of gel.
	Purity (2) Starch	Sample weighing procedure modified.	It is not necessary to weigh the sample accurately.
	Purity (4) Heavy metals	Specification abolished.	Harmonization with JECFA standards.
	Purity (5) Lead	Limit is revised. (Not more than 10.0 µg/g → Not more than 2.0 µg/g)	Harmonization with JECFA standards.
Calcium Citrate	Purity (Residual solvent: 2-Propanol)	Specification newly set. (Not more than 1.0%)	Harmonization with JECFA standards.
	Purity (2) Clarification	pH 6.0—8.0 → pH 5.5—8.0	pH of ground products is lower.
	Purity (5) Heavy metals	Method replaced by Method 2. (Sample fully ignited before the preparation of test sample.)	Colorimetric tests are not appropriate, because the test solution is colored.
Glycerol Esters of Fatty Acids	Identification (1)	Method modified.	Modification of sample preparation.
	Identification (3)	Current test method replaced by HPLC method.	Improvement of procedure and accuracy.
Zinc Gluconate	Purity (1) Heavy metals	Specification abolished.	Elimination of harmful reagents (potassium cyanide).
	Purity (Lead)	Specification newly set. (Not more than 10 µg/g)	
Baking Powder (3 substances)	Purity (1) Nitric acid-insoluble substances	Test method modified.	Elimination of asbestos, which is used for Gooch crucible.
Acetic Acid	Description	Specification for taste abolished.	Ease of examiners' burden.
Polyvinyl Acetate	Identification (IR Spectrophotometry)	Solvent is replaced (Toluene → Ethyl Acetate)	Improvement of the accuracy of identification.
Benzyl Acetate	Identification	Qualitative reaction → Comparison to IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Methyl Salicylate	Identification (IR Spectrophotometry)	Identification by wavenumbers → Comparison to IR reference Spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Shellac	Purity (4) Rosin	Solvent replaced by less harmful one.	Elimination of harmful reagents
	Purity (5) Wax	Solvent replaced by less harmful one.	Elimination of harmful reagents

Gellan Gum	Definition	Source bacterial strain changed. Scientific name added.	Change of nomenclature.
	Description	Color range expanded to white.	Color may change depending of particle size and the degree of refinement.
	Purity (2) Heavy metals	Specification abolished.	Harmonization with JECFA standards.
	Purity (3) Lead	Significant digit of the limit modified.	Significant digit number changed. Harmonization with JECFA standards.
	Purity (Residual solvent: 2-Propanol)	Specification newly set. (Not more than 0.075%)	Harmonization with JECFA standards.
Allyl Cyclohexylpropionate	Identification	Qualitative test → Comparison to IR reference spectrum	Improvement of the accuracy of identification.
1,8-Cineole	Identification	Qualitative test → Comparison to IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Sucrose Esters of Fatty Acids	Purity (6) Resorcinol	Mercuric nitrate replaced by another reagent.	
	Identification (1)	Esters of fatty acid and sucrose and sucrose acetate isobutyrate are distinguished from each other.	Necessary to establish specifications for residual solvents.
	Purity (2) Dimethyl formamide	Test method modified.	Elimination of harmful reagents.
	Purity (3) Heavy metals	Specification abolished.	Harmonization with JECFA standards.
	Purity (Lead)	Specification newly set. (Not more than 2.0 µg/g as Pb)	Harmonization with JECFA standards.
	Purity (Dimethyl sulfoxide)	Specification newly set. (Not more than 2 µg/g; not applied to sucrose acetate isobutyrate)	Harmonization with JECFA standards.
	Purity (Other solvents)	Specifications newly set. (Not applied to sucrose acetate isobutyrate)	Harmonization with JECFA standards.
	Ethyl acetate, 2-Propanol, and Propylene glycol	Not more than 350 µg/g	
	Ethyl methyl ketone	Not more than 10 µg/g	
	Methanol	Not more than 10 µg/g	
Silicone resin	2-Methyl-1-propanol	Not more than 10 µg/g	
	Identification (IR Spectrophotometry)	Identification by wavenumbers → Comparison to IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Annatto, Water-soluble	Identification (1)	Antimony trichloride replaced by less harmful	Elimination of harmful reagents.
	Purity (5) Arsenic	Method 2, Apparatus B → Method 4, Apparatus C	Harmonization with JECFA standards.

Purified Carrageenan	Definition	Source algae's scientific name added	Clarification of source algae
	Identification (2)	Specification abolished	This test is to see gelling properties. The test does not match characteristics of commercial purified carrageenan.
	Purity (1) Viscosity	Heating process before sampling eliminated. Sampling of the amount equivalent to dry weight.	Viscosity falls during drying.
	Purity (2) Sulfate	Test method modified (sample is pretreated to remove the excipient).	Harmonization with JECFA standards.
	Purity (3) Acid-insoluble matter	Test method modified (sample is pretreated to remove the excipient).	Harmonization with JECFA standards.
	Purity (5) Lead	Limit revised (not more than 10 µg/g → not more than 5.0 µg/g)	Harmonization with JECFA standards.
	Purity (Residual solvent: 2-Propanol and methanol)	Specification newly set. (Not more than 0.10% in total)	Harmonization with JECFA standards.
	Ash	Test method modified (sample is pretreated to remove the excipient).	Harmonization with JECFA standards.
Sorbitan Esters of Fatty Acids	Acid-insoluble ash	Test method modified (sample is pretreated to remove the excipient).	Harmonization with JECFA standards.
	Purity (4) Polyoxyethylene	Solvent replaced by less harmful one	Elimination of harmful reagents.
D-Sorbitol	Assay	Internal standard method → Absolute calibration curve method	Harmonization with JECFA standards.
D-Sorbitol Syrup	Content	Limit revised.	Harmonization between specifications for content and specific gravity. Current specifications (content: 50.0% – 70.0%) and (specific gravity: 1.285 – 1.315) do not align with each other.
	Purity (1) Specific gravity	Measurement temperature changed. (20°C → 25°C)	Harmonization with FCC.
Demmar Resin	Definition	Scientific name added.	Clarification of source plants.
	Identification (2)	Solvent replaced by less harmful one	Elimination of harmful reagents.
	Purity (3) Iodine value	Solvent replaced by less harmful one	Elimination of harmful reagents.
Ethyl Decanoate	Identification (1), (2)	Qualitative reaction → Comparison to IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Dunaliella Carotene	Identification (1)	Solvent replaced by less harmful one.	Elimination of harmful reagents.
	Identification (2)	Solvent replaced by less harmful one	Elimination of harmful reagents.
Paprika Color	Identification (4)	Solvent replaced by less harmful one	Elimination of harmful reagents.

<i>d</i> -α-Tocopherol	Definition	Newly added.	Harmonization with <i>d</i> -γ- and <i>d</i> -δ-Tocopherols, which are newly added to the 8th Edition.
	Purity (2) Acid value	Sampling amount modified (10g → 2.5 g)	Revision of the determination method of acid value.
<i>dl</i> -α-Tocopherol	Assay	Test method modified.	Clarification of assay method.
	Content	Content revised.	Revision in step with the revision of assay method.
Trypsin	Assay	Titration method replaced by HPLC.	Harmonization with the Japanese Pharmacopoeia and standards for natural vitamin E.
	Purity (1) Heavy metals	Specification abolished.	Harmonization with JECFA standards.
Carrot Carotene	Purity (2) Lead	Limit revised. (Not more than 5.0 µg/g)	Harmonization with JECFA standards.
	Identification (1)	Solvent replaced by less harmful one.	Elimination of harmful reagents.
γ-Nonalactone	Identification (2)	Solvent replaced by less harmful one.	Elimination of harmful reagents.
	Identification	Qualitative reaction → Comparison to IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Papain	Purity (1) Heavy metals	Specification abolished.	Harmonization with JECFA standards.
	Purity (2) Lead	Limit revised. (Not more than 5.0 µg/g)	Harmonization with JECFA standards.
Palm Oil carotene	Identification (1)	Solvent replaced by less harmful one.	Elimination of harmful reagents.
	Identification (2)	Solvent replaced by less harmful one	Elimination of harmful reagents.
<i>p</i> -Methylacetophenone	Identification (IR Spectrophotometry)	Identification by wavenumbers → Comparison to IR reference Spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Vitamin A Esters of Fatty Acids	Identification (1)	Method replaced by TLC.	Elimination of harmful reagents.
	Purity (2) Chloroform-insoluble substances	Specification abolished.	Elimination of harmful reagents. Specification does not match the current manufacturing method.
	Purity (3) Absorbance ratio	Concentration of the test solution revised.	The current concentration of test solution is not appropriate to determine absorption spectrum.
Vitamin A in Oil	Identification (1)	Method replaced by TLC.	Elimination of harmful reagents.
	Purity (2) Chloroform-insoluble substances	Specification abolished.	Elimination of harmful reagents. Specification does not match the current manufacturing method.
Beet Red	Identification (3)	Wavelength revised. 525–535 → 525–540nm	Adjustment of maximum wavelength.
Isobutyl Phenylacetate	Identification (1), (2)	Qualitative test → IR Reference Spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Isobutyl Phenylacetate	Identification (1), (2)	Qualitative test → IR Reference Spectrum (Liquid Film Method)	Improvement of the accuracy of identification.

Propylene Glycol	Identification	Qualitative test → IR Reference Spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Propylene Glycol Esters of Fatty	Identification (2)	Solvent replaced by less harmful one.	Elimination of harmful reagents.
	Purity (4) Polyoxyethylene	Solvent replaced by less harmful one.	Elimination of harmful reagents.
Bromelain	Purity (1) Heavy metals	Specification abolished.	Harmonization with JECFA standards.
	Purity (2) Lead	Limit revised. (Not more than 5.0 µg/g)	Harmonization with JECFA standards.
Dry Formed Vitamin A	Identification	Test method replaced by TLC.	Elimination of harmful reagents.
Pectin	Definition	Definition clarified.	Harmonization with JECFA standards.
	Identification (1), (2), (3)	Test methods replaced by a new method making use of enzyme.	Harmonization with JECFA standards.
	Purity (3) Heavy metals	Specification abolished.	Harmonization with JECFA standards.
	Purity (4) Total nitrogen	Acidic alcohol-washing process applied to the sample before Semi-micro Kjeldahl test.	Improvement of test method.
	Purity (5) Lead	Limit revised. (Not more than 10 µg/g → not more than 5.0 µg/g)	Harmonization with JECFA standards.
	Purity (Total insolubles)	Specification for "ash" (not more than 10.0%) abolished, total insolubles (not more than 3.0%) added.	Harmonization with JECFA standards.
	Purity (Residual solvent: 2-Propanol and methanol)	Specification newly set. (Not more than 1.0% in total)	Harmonization with JECFA standards.
	Loss on drying	Test method modified. (105°C, 5 hours → 105°C, 2 hours)	Harmonization with JECFA standards.
	Ash	Specification abolished.	Harmonization with JECFA standards.
Pepsin	Purity (1) Heavy metals	Specification abolished.	Harmonization with JECFA standards.
	Purity (2) Lead	Limit revised. (5.0 µg/g)	Harmonization with JECFA standards.
Benzaldehyde	Identification (1), (2)	Qualitative reaction → Comparison to IR Reference Spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Polysobutylene	Purity (5) Total unsaturated substances	Solvent replaced by less harmful one.	Elimination of harmful reagents.
	Purity (6) Low molecular weight polymer	Solvent replaced by less harmful one.	Elimination of harmful reagents.
Polyvinylpyrrolidone	Identification (1)	Specification abolished.	
	Identification (2) IR Spectrophotometry	Identification by wavenumbers → Comparison to IR reference Spectrum (Paste Method)	Improvement of the accuracy of identification.
Mangold Color	Identification (3)	Solvent replaced by less harmful one.	Elimination of harmful reagents.

Maltol	Identification (IR Spectrophotometry)	IR Reference Spectrum (KBr Method → Paste Method)	Improvement of the accuracy of identification.
D-Mannitol	Assay	Internal Standard Method replaced by Absolute Calibration Curve Method.	Harmonization with JECFA standards.
Mixed Tocopherols	Purity (2) Acid value	Amount of sample revised. (10g → 2.5g)	Modification of the determination method of acid value.
	Assay	Test method modified.	Clarification of test method.
DL-Methionine	Identification (1), (2), (3), (4)	Qualitative reaction → IR reference spectrum (KBr Method)	Improvement of the accuracy of identification.
L-Methionine	Identification (1), (2), (3), (4)	Full procedure is written and test procedures themselves are not revised.	
Methyl β-Naphthyl Ketone	Identification (1), (2)	Qualitative reaction → IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Morpholine Salts of Fatty Acids	Identification (1)	Method revised to eliminate the use of benzen.	Elimination of harmful reagents.
Folic Acid	Purity: Free amine	Test method modified.	Adjustment of multiplying factor of dilution.
Zinc Sulfate	Purity (2) Heavy metals	Specifications abolished.	Elimination of harmful reagents.
	Purity (Lead)	Specification newly set.	
Ferrous Sulfate	Purity (1) Clarity of solution	pH: Acidity of not lower than 3.7 → Not lower than 3.4	pH is made to conform to the acidity of commercial products. (pH varies depending on viscosity.)
Liquid Paraffin	Identification (IR Spectrophotometry)	Identification by wavelengths → Comparison to IR reference spectrum (Liquid Film Method)	Improvement of the accuracy of identification.
Tricalcium Phosphate	Molecular structure, Molecular weight	Abolished.	Molecular formula and weight do not conform to commercial products.
	Definition	Definition added.	Identity is made clear.
	Content	Molecular weight added.	Description of content is made to conform to commercial products.

Lecithin	Description	Modified	Harmonization with the manner for description.
	Identification (1)	Use of the method for Enzymatically Decomposed Lecithin.	Harmonization with specifications for Enzymatically Decomposed Lecithin, which is added to the 8th Edition.
	Purity (3) Acetone-soluble substances	Use of the method for Enzymatically Decomposed Lecithin.	Harmonization with specifications for Enzymatically Decomposed Lecithin.
	Purity (4) Peroxide value	Use of the method for Enzymatically Decomposed Lecithin.	Harmonization with specifications for Enzymatically Decomposed Lecithin.
	Water	Abolished. Specification for "loss on drying" added.	Elimination of harmful reagents.

Note: 1. IR: Infrared, IR Spectrum: Infrared spectrum
 2. KBr Method: Potassium Bromide Disk Method
 3. JECFA standards: standards established by the FAO/WHO Joint Expert Committee on Food Additives.
 4. FCC: Food Chemicals Codex, a publication on specifications for food additives, which is compiled by Food and Nutrition Board, Institute of Medicine, National Academy of Sciences.
 5. TLC: Thin-Layer Chromatography
 6. GC: Gas Chromatography
 7. HPLC: High Performance Liquid Chromatography

Table3

Outline of the Revision of Monographs (Substances Designated after the Publication of the 7th Edition)

Substance name	Category	Outline of revision	Reason of revision
L-Ascorbic Acid 2-Gluconide	Identification (1), (2)	Abolished.	Abolishment in step with revision of Identification (1).
	Identification (3)	Identification by wavenumbers → Comparison to IR reference spectrum (KBr Method)	Improvement of the accuracy of identification.
Sucralose	Identification (2)	Abolished.	This test is unnecessary because identification by IR spectrophotometry (comparison to IR reference spectrum) is enough.
	Purity (1) Clarity of solution	Abolished.	Harmonization with JECFA standards.
	Purity (3) pH	Abolished.	Harmonization with JECFA standards.
	Purity (4) Heavy metals	Abolished.	Harmonization with JECFA standards.
	Purity (Lead)	HML Test replaced by LL Test. (Not more than 1.0 µg/g)	Harmonization with JECFA standards.
	Purity (5) Arsenic	Method 2, Apparatus B → Method 4, Apparatus C	Harmonization with JECFA standards.
Calcium Stearate	Purity (2) Arsenic	Sampling amount modified (1.0g → 0.50g)	Correction of error of test method.
Ferrocyanides	Purity (2) Ferricyanide salts	Abolished.	Elimination of harmful reagents.
Trimagnesium Phosphate	Identification	Current method replaced another new methods. (Identification (1) (2))	The revision is made to ensure identification.
	Purity (1) Clarity of solution	Slightly modified. Slightly turbid → Turbid	The revision is made to conform to commercial products.
	Purity (2) Heavy metals	Method modified.	Improvement of method.